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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/781,577 | 02/12/2001 | Irene E. Kochevar | 10284-018001 | 9723 |
| 20999 | 7590 | 07/19/2004 | EXAMINER | |
| FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151 | | | BARRETT, THOMAS C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3738 | |

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|---------------------------------|--|
| Office Action Summary | Application No. 09/781,577 | Applicant(s) KOCHEVAR ET AL. | |
| | Examiner Thomas C. Barrett | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Response to Arguments***

Applicant's arguments filed April 5, 2004 have been fully considered but they are not persuasive. The Applicant arguments are directed towards non-enablement and that "Khadem provides no reasonable expectation of success for methods of producing a tissue seal without administration of an exogenous cross-linkable substrate."

MPEP 2143.02 states that "Obviousness requires only a reasonable expectation of success"

Apparently the Applicant is using an argument of non-obviousness in trying to overcome an anticipatory rejection.

As the Applicant points out, Khadem states that its methods can be applied to a variety of tissues including the cornea and other tissues of the eye (column 8 line 29 and Example 8). Khadem discloses, beginning at column 8 line 23, that, "The present invention is envisioned to be suitable for use..." and the present invention includes the invention encompassed at column 7 lines 18-30.

The declaration under 37 CFR 1.132 filed April 5, 2004 is insufficient to overcome the rejection of claims 1-20, and 23 based upon Khadem et al. (5,552,452) as set forth in the last Office action because: The declaration states, "it is my opinion, as one of ordinary skill in the art, who has read the Khadem patent, that portions of the patent ***other than*** column 7 lines 18-30 cannot be relied upon for additional instruction because they are solely intended for methods that require application of an exogenous substrate" (emphasis added). Therefore the declaration admits the "four sentences" are

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directed to methods that do not require application of exogenous substrates. As can be seen in Table 2, titled PROTEIN/PHOTOSENSITIZER MIXTURES, photosensitizers alone, i.e. Rose Bengal (1mM) had been used. Furthermore, where the declaration presented asserts that the reference relied upon is inoperative (i.e. the use of methylene blue), the claims represented by applicant must distinguish from the alleged inoperative reference disclosure. Declarations attacking the operability of a patent cited as a reference must rebut the presumption of operability by a preponderance of the evidence. In addition, the present Application states in Example 5 that the method is ***inefficient***, not ***ineffective***.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness and non-enablement fail to overcome the Khadem et al. reference.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14, 17-20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Khadem et al. (5,552,452) as cited in applicant's IDS. Khadem et al. discloses a method for adhering tissue comprising: contacting a tissue with a photosensitizer, creating a tissue-photosensitizer mixture, applying electromagnetic

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energy without more than a 1 degree rise in temperature (col. 3, line 67- col. 4, line 3), and creating a tissue seal without contacting the tissue with an exogenous cross-linkable substrate (col. 7, lines 18-30). The method may comprise the use of Rose Bengal and energy applied at 600-670 nm (Table 1) or a thiazine (col. 4, line 64- col. 5, line 3), and can be used for refractive surgery (col. 8, lines 3-8). The methods can be used on humans and in vivo or ex vivo (col. 15, lines 39-47).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-16 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khadem et al. (5,552,452). Khadem et al. discloses a method for adhering tissue comprising: contacting a tissue with a photosensitizer, creating a tissue-photosensitizer mixture, applying electromagnetic energy without more than a 1 degree rise in temperature however Khadem et al. fails to disclose specific W/cm, and J/cm ranges. MPEP 2144.05 states:

II. OPTIMIZATION OF RANGES

A. Optimization Within Prior Art Conditions or Through Routine Experimentation

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such

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concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

The general conditions of the claims are disclosed in Khadem et al. Khadem et al. discloses adhering tissue using a laser at wavelengths greater than 488 nm and a photosensitizer under conditions that minimize tissue damage (col. 2, lines 55-67). Lasers are well known in the art to have controllable energy doses and irradiances, such as the commercial ones admitted to by the Applicant (pp 15-16). The optimum ranges of energy doses and irradiances can easily be found through routine experimentation. It would have been obvious to one of ordinary skill in the art to combine the teaching of routine experimentation to determine the optimum ranges of energy doses and irradiances, to a method for adhering tissue as per Khadem et al., in order to minimize tissue damage.

In addition, Khadem discloses, "Likewise, the application of the electromagnetic radiation will also be adapted to suit the particular circumstances of operation. It is generally envisioned that the time for performing a tissue closure procedure in accordance herewith will be less than five minutes in total." The optimum length of application of the electromagnetic radiation can easily be found through routine experimentation (col. 7, lines 31-45). It would have been obvious to one of ordinary skill in the art to combine the teaching of routine experimentation to determine the optimum length of application of the electromagnetic radiation, to a method for adhering tissue as per Khadem et al., in order to ensure tissue closure.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (703) 308-8295. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703) 308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read "Thomas Barrett", with a stylized flourish at the end.

Thomas Barrett